



QA CONTRACT CONTENT

PROCEDURE ID: YMP-LBNL-QIP-4.1

REV.2, MOD.0

EFFECTIVE: 6/2/97

1. PURPOSE

This quality implementing procedure (QIP) establishes measures to ensure that contracts for quality affecting work include or reference the applicable quality assurance (QA), technical, and site characterization requirements that are necessary to ensure adequate quality in scientific investigations of the Yucca Mountain Site Characterization Project at Ernest Orlando Lawrence Berkeley National Laboratory (YMP-LBNL).

2. SCOPE

This procedure applies to the preparation of contract content for the procurement of services from non-LBNL sources and organizations outside the YMP-LBNL-QIP-1.0, line of authority as defined in the scope of YMP-LBNL QIP 4.0.

3. PROCEDURE

- 3.1 When a YMP-LBNL organization or office needs the services of a support organization, the responsible requester [typically a YMP-LBNL Principal Investigator (PI)] shall plan and develop, with the aid of an appropriate LBNL buyer, a contract, taking into consideration the topics stated in Attachment 1. Requirements shall be included relative to the level of importance, complexity, and quantity of the service being requested and the supplier's quality performance.
- 3.2 Suppliers of services shall be on the YMP Qualified Suppliers List (QSL) or, if the time needed to evaluate and add the supplier to the QSL could result in an irrecoverable loss of data, the supplier shall follow YMP-LBNL QIPs and technical implementing procedures (TIPs) until such evaluation is complete. Development and maintenance of the YMP QSL is covered in Office of Civilian Radioactive Waste Management (OCRWM) Administrative Procedure AP-7.4Q.
- 3.3 All review and approval requirements shall be met prior to support organizations providing services. Approvals shall include the originating requester, the YMP-LBNL Engineering Assurance (EA) Manager, OQA Representative, and the Project Manager (PM) or their respective designee on Attachment 2 of YMP-LBNL QIP 4.0. The approval of appropriate support organization management shall be obtained by signature on the contract.

- 3.4 Changes/modifications/addenda to contract require the same review and approval as the original document. Upon approval of such revisions, the PM or designee shall re-distribute the agreement with its changes and review forms to signatories.

4. RECORDS MANAGEMENT

4.1 Lifetime

Support Organization Agreement
Changes/modifications/addenda to agreement

4.2 Non-permanent

None

4.3 Controlled Documents

None

4.4 Records Center Documents

Records associated with this procedure shall be submitted to the YMP-LBNL Local Records Processing Center, in accordance with YMP-LBNL-QIP-17.0 and AP-17.1Q.

5. RESPONSIBILITIES

- 5.1 **Project Manager (PM)**, who is the Nuclear Waste Department Head, or designee, is responsible for the oversight of agreements directly supporting YMP-LBNL, and for the approval of other office agreements and their technical, programmatic, and budgetary review. He/she is also responsible for distributing approved agreements to signatories.
- 5.2 **YMP-LBNL Engineering Assurance (EA) Manager**, or designee, is responsible for the EA review and approval of agreements.
- 5.3 **The Office of Quality Assurance (OQA) representative** or designee is responsible for reviewing all procurements for compliance with the applicable QARD requirements.
- 5.4 **Requester**, typically a Principal Investigator or designee, is responsible to plan and develop the initial agreement, taking into consideration the topics stated in Attachment 1.
- 5.5 **Administrative Office (AO)** is responsible for processing the agreement through LBNL administrative procedures and forwarding it to the LBNL Purchasing Department.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms.

AO	Administrative Officer
QSL	Qualified Supplier List
OQA	Office of Quality Assurance

6.2 Definitions

Contract. A written agreement which states the requirements, procedures, conditions, and payment arrangements of an acquisition from a supplier. This Contract may be referred to as a management agreement, memorandum of agreement, a memorandum of understanding, task agreement, or similar name.

Support Organization. An organization providing a specific quality-affecting service to the YMP-LBNL.

7. REFERENCES

- DOE/RW-0333P,R5, *Quality Assurance and Requirements Description*
- AP-7.4Q, *Maintenance of the OCRWM Qualified Suppliers List*
- AP-17.1Q, *Record Source Responsibilities for Inclusionary Records*
- QAP 1.1, *Organization*
- YMP-LBNL-QIP-1.0, *Organizational Structure*
- YMP-LBNL-QIP-4.0, *Contract Development*
- YMP-LBNL-QIP-17.0, *Submitting Records to the YMP-LBNL Records Processing Center*

8. ATTACHMENTS

Attachment 1: Topics to be Included in Agreements, as Applicable

9. REVISION HISTORY

9/22/95 - Revision 0, Modification 1:

Addressed lifetime and non-permanent records.

10/21/96 - Revision 1, Modification 0:

Revised procedure to reflect requirements changes in QARD, Rev. 5.

Changed name of procedure to more accurately reflect contents.

Made general improvements and corrections.

6/2/97 -Revision 2, Modification 0:

Revised procedure to introduce the term Engineering Assurance (EA) and to identify the role and responsibilities of the EA Manager and OQA representative.

10. APPROVALS

Preparer:

Date

Technical Reviewer:

Date

Technical Reviewer:

Date

QA Reviewer:

Date

QA Manager:

Date

Project Manager:

Date

TOPICS TO BE INCLUDED IN CONTRACTS, AS APPLICABLE

- A. Site Characterization Plan (SCP), and WBS numbers.
- B. Effective date and termination date of contract.
- C. Funds: amount, method of payment.
- D. Documentation of supplier personnel qualifications.
- E. Statement of scope of work, including the identification of what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished including actions and milestones.
- F. Technical requirements:
 - 1. Design or planning bases shall be identified or referenced.
 - 2. Specific documents (such as drawings, codes, standards, regulations, procedures or instructions) that describe the technical aspects of the services to be furnished shall be specified. The revision level or change status of these documents shall also be identified.
 - 3. Tests, inspections, milestones, and other acceptance requirements that will be used to monitor and evaluate the performance of the supplier shall be specified.
 - 4. If calibration is an element of the agreement, the supplier shall provide evidence of calibration procedures and the ability to provide YMP-LBNL with calibration documentation.
- G. Quality assurance requirements:
 - 1. A requirement for the supplier to comply with the YMP-LBNL quality assurance (QA) Program or a requirement for the supplier to have documented procedures or practices that implement applicable Quality Assurance and Requirements Description (QARD) requirements prior to the initiation of work. The extent of the QA program shall depend on the scope, nature, or complexity of the service being procured.
 - 2. A requirement for quality-affecting procurements to be processed for the supplier by YMP-LBNL or a requirement for the supplier to identify quality-affecting procurements in the text of the agreement and provide for YMP-LBNL approval and OQA concurrence.
 - 3. When deemed appropriate, YMP-LBNL shall permit some or all supplier work to be performed under the supplier's documented procedures or practices provided the work is adequately addressed by those procedures or practices.

4. In some cases, procurement documents shall specify that YMP-LBNL implementing documents are applicable to the supplier. When appropriate, YMP-LBNL shall provide these documents and training.
- H. Right of access to supplier records and facilities for inspection and/or audit by the YMP-LBNL, DOE personnel or their representatives.
- I. Provisions for establishing witness points and hold points beyond which work cannot proceed without YMP-LBNL authorization.
- J. A document submittal schedule shall be identified for documents requiring submittal to YMP-LBNL for information, review, or acceptance.
- K. The supplier shall provide evidence of the ability to control records, as prescribed in YMP-LBNL-QIP-17.0, and AP-17.1Q including the retention times and disposition requirements.
- L. YMP-LBNL requirements for the supplier to report nonconformances and YMP-LBNL approval of the disposition of nonconformances.
- M. Provisions for regular reporting of expenditures and work accomplished, and any special circumstances or problems.
- N. Provisions for amending work scope and funding.
- O. Supplier Performance Evaluation
 1. YMP-LBNL shall establish measures to interface with the supplier and to verify performance. The measures shall include:
 - Establishing an understanding between YMP-LBNL and supplier of the requirements and specifications identified in the agreement.
 - Requiring the supplier to identify planning techniques and processes to be used in fulfilling the terms of the agreement before conducting activities requiring control.
 - Reviewing supplier documents that are prepared or processed during work performed to fulfill the terms of the agreement.
 - Identifying and processing necessary change information.
 - Establishing the method to be used to document information exchanges.

2. The extent of YMP-LBNL verifications shall be a function of the relative importance, complexity, and quantity of services being procured, and the supplier's quality performance.
3. The verification measures selected from the above shall be conducted as early as practical once the service is initiated. Any verification measure conducted by the YMP-LBNL shall not relieve the supplier of the responsibility for the verification of quality achievement. Evaluation of documentation to aid in the determination of the effectiveness of the supplier's quality assurance program shall be part of the verification.
4. Methods for accepting supplier furnished services shall be complete before the service is accepted and shall include one or more of the following, as appropriate to the service being procured:
 - evaluation of the supplier certificate of conformance;
 - source verification implemented at predetermined points. If source verification is to be used, identify elements to be verified.
 - technical verification of the service;
 - surveillance or audit of the work;
 - evaluation of objective evidence for conformance to the procurement document requirements;

4.1. When a certificate of conformance is used;

1. The certificate shall identify:
 - the purchased service to the specific procurement document;
 - the specific procurement document requirement met by the purchased service and any approved changes, waivers, or deviations from the requirements;
 - procurement document requirements not met and their justification of means for resolving the nonconformance.
2. The certificate shall be authenticated by a person responsible for the QA function and whose responsibilities and position are described in the supplier's quality assurance program.
3. The certification process, including implementing documents shall be described in the supplier's QA program.

4. Measures to verify the validity of the supplier's certificates and the effectiveness of the certification process shall be identified. YMP-LBNL shall request OQA to conduct such verifications at intervals commensurate with the past quality performance of the supplier.

4.2 When source verification is used:

YMP-LBNL may accept a service by monitoring, witnessing, or observing activities performed by the supplier.

- The verification shall be implemented consistent with the planned inspections, examinations or tests at predetermined points consistent with the importance and complexity of the service.
- Source Verifications shall be performed by OQA and coordinated with appropriate technical personnel as necessary.
- Source Verifications will be documented on Surveillance reports by OQA and will be furnished to the YMP-LBNL for consideration during acceptance of services.